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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/656,803	09/04/2003	Warner C. Greene	UCAL-283	7086

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EXAMINER	
BOESEN, AGNIESZKA	
ART UNIT	**PAPER NUMBER**
1648	

DATE MAILED: 03/30/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/656,803	GREENE ET AL.	
	Examiner	Art Unit	
	Agnieszka Boesen	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 December 2005*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-31* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-31* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-15, drawn to a **method for detecting fusion of an enveloped retrovirus to a target cell**, the method comprising contacting a target cell with an enveloped retroviral virion containing a chimeric viral protein comprising a reporter polypeptide, classified in class 435, subclass 5.

II. Claims 16-19, drawn to a **method for identifying an agent that modulates fusion of HIV virion to a target cell**, the method comprising contacting a target cell with a candidate agent and with an HIV virion containing a chimeric viral protein, classified in class 435, subclass 5.

III. Claims 20-22, drawn to a **method for identifying a viral envelope protein that facilitates viral fusion to a target cell**, the method comprising contacting a target cell with a pseudotyped HIV virion, classified in class 435, subclass 5.

IV. Claim 23, drawn to a **method for identifying a viral envelope protein**, wherein the method further comprises contacting the target cell with a candidate agent that facilitates viral fusion to a target cell, classified in class 435, subclass 5.

V. Claims 24, and 25, drawn to an **isolated chimeric viral protein**, classified in class 530, subclass 300.

VI. Claim 29, drawn to an **isolated enveloped virion**, classified in class 424, subclass 207.1

VII. Claims 26, 27 and 28, drawn to an **isolated polynucleotide sequence**, classified in class 536, subclass 23.1.

VIII. Claims 30 and 31, drawn to a **kit** for detecting fusion of an enveloped virion to a target cell, classified in class 424, subclass 207.1.

2. The inventions are distinct, each from the other because of the following reasons:

Inventions I, II, III, and IV are directed to related method for detecting fusion of an enveloped retrovirus to a target cell, the method for identifying an agent that modulates fusion of HIV virion to a target cell and a method for identifying a viral envelope protein that facilitates viral fusion to a target cell. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant

different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case, the method for detecting fusion of an enveloped retrovirus to a target cell, and the method for identifying an agent that modulates fusion of HIV virion to a target cell do not overlap with a method for identifying a viral envelope protein that facilitates viral fusion to a target cell. The method for detecting fusion of an enveloped retrovirus to a target cell of Group I and the method of identifying an agent that modulates fusion of HIV virion to a target cell of Group II have a different function than the method o identifying viral envelope protein that facilitates viral fusion to a target cell. The methods of Groups I, II, II, and IV have different method steps and use different reagents. A search for a method of identifying a viral envelope protein that facilitates viral fusion to a target cell of Group III is not co-extensive with a search for a method further comprising contacting the target cell with a candidate agent that facilitates viral fusion to a target cell of Group IV.

Because these inventions are independent or distinct for the reasons given above and the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

The protein of Group V and polynucleotide of Group VII are related. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case, polypeptides, which are composed of amino acids, and polynucleotides, which are composed of purine and pyrimidine units, are

structurally distinct molecules; any relationship between a polynucleotide and polypeptide is dependent upon the information provided by the nucleic acid sequence open reading frame as it corresponds to the primary amino acid sequence of the encoded polypeptide. Furthermore, the information provided by the polynucleotide of Group VII can be used to make a materially different peptide than that of Group V. For example the polynucleotide sequence that hybridizes to the polynucleotide of Group VII will not encode the protein of Group V. In addition, while a protein of Group V can be made by methods using some, but not all, of the polynucleotides that fall within the scope of Group VII it can also be recovered from a natural source such as by using biochemical means. For instance, the polypeptide can be isolated using affinity chromatography. For these reasons, the inventions of Groups V and VII are patentably distinct.

Furthermore, searching the inventions of Groups V and VII together would impose a serious search burden. In the instant case, the search of the peptide and the polynucleotides are not coextensive. The inventions of Groups V and VII have a separate status in the art as shown by their different classifications. There is search burden also in the non-patent literature. Prior to the concomitant isolation and expression of the sequence of interest there may be journal articles devoted solely to peptides, which would not have described the polynucleotide. Similarly, there may have been "classical" genetics papers, which had no knowledge of the polypeptide but spoke to the gene. Searching, therefore is not coextensive.

The virus of group VI, the protein of Group V, and the polynucleotide of group VII are patentably distinct inventions for the following reasons. In the instant case, the virus and the protein or the polynucleotide do not overlap in scope because the virus, which is a

microorganism, and the protein or the polynucleotide, are different products having different structures and different functions. The microorganism is a living entity and the protein or a polynucleotide are the isolated structures. The virus has a complex structure composed of nucleic or ribonucleic acids together with the structural proteins, whereas the polynucleotide alone is composed of purine and pirimidine units, and the protein is composed of amino acids. In addition to the distinctiveness of the invention of Groups VI, V, and VII searching the inventions of Groups VI, V, and VII would impose a serious search burden. For example, the virus and the protein or the polynucleotides have a separate status in the art as shown by their different classifications. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Inventions (V, VI, VII) and VIII are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the subcombination has utility by itself or in other combinations. The subcombinations, such as the isolated chimeric viral protein, an isolated polynucleotide sequence, and an isolated enveloped virion have separate utility such as in the method of immunization against the retroviral disease. Further, the combination as claimed does not require the particulars of the subcombination as claimed for patentability. The kit requires at least the chimeric viral protein of claim 24, an isolated vector comprising a polynucleotide

sequence encoding the chimeric viral protein, or an isolated enveloped virion containing the chimeric viral protein. The kit only optionally contains the particulars of the subcombinations. In some embodiments, the kit only contains an enveloped virion containing the chimeric viral protein. A search for this embodiment of the kit is not coextensive for a search for a polynucleotide encoding the chimeric viral protein for the reasons explained above. A search for the embodiment of the kit wherein the kit only contains an isolated vector comprising a polynucleotide sequence encoding the chimeric viral protein is not coextensive for a search for the enveloped virion containing the encoded chimeric viral protein, also for the reasons set forth above.

A search for a viral protein, an isolated polynucleotide sequence, and an isolated enveloped virion peptide sequences is not co-extensive with a search for the kit comprising the above mentioned products. It would be a serious burden for the examiner to search more than one invention. Therefore restriction for examination purposes is proper.

The protein of Group V, the polynucleotide of Group VII and the methods of Group (I, II, III, IV) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case, the protein or the polynucleotide can be used in a materially different process such as to induce the immune responses in a mammal. A search for a protein or the polynucleotide is not co-extensive with a search for a method for detecting fusion of an enveloped retrovirus to a

target cell, the method for identifying an agent that modulates fusion of HIV virion to a target cell and a method for identifying a viral envelope protein that facilitates viral fusion to a target cell. It would be a serious burden for the examiner to search more than one invention. Therefore restriction for examination purposes is proper.

Furthermore, searching the inventions of Groups (V, VII) and Group (I, II, III, IV) would impose a serious search burden. The inventions have a separate status in the art as shown by their different classifications. An amino acid sequence search of the full-length protein is necessary for a determination of novelty and unobviousness of the protein. However, such a search is not required to identify the antibodies of Group I. In addition, the technical literature search for the antibodies of Group I and the protein of Group IV are not coextensive, e.g., antibodies may be characterized in the technical literature prior to discovery of or sequence of their binding target. Therefore restriction for examination purposes is proper.

The virion of Group VI, the kit of Group VIII and the methods of Group (I, II, III, IV) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case, the infection in a mammal can be treated with a materially different product such as antibiotics. A search for peptide sequences is not co-extensive with a search for a method of use of the composition comprising the peptides. It would be a serious burden for the examiner to search more than one invention. Therefore restriction for examination purposes is proper.

3. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re Brouwer and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so**

may result in a loss of the right to rejoinder. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Agnieszka Boesen, Ph.D. whose telephone number is 571-272-8035. The examiner can normally be reached on M – F (9:00AM – 5:30PM). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

AB

Agnieszka Boesen, Ph.D.
March 27, 2006

Stacy B. Chen 3/27/06
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